K980806

AFFINITY

510(k) Summary
Prepared 3/17/98

MAR 25 1998

1. **Manufacturer:**
Affinity Medical Technologies, LLC
17332 Von Karman, Suite 115
Irvine, CA 92614
714-477-9495
Contact: Mary F. Phillipp

2. **Trade Name**: Affinity Medical Patient Cable Systems
Common Name: Patient Cable [cable, transducer and electrode, patient (including connector)]
Classification: Class II
74DSA (CFR 870.2900)

3. **Predicate Device**: This device is substantially equivalent to the Tronomate™ Patient Cable and Leadwire System (K952659).

4. **Description:** The Affinity Cable and Leadwire System includes ECG cables, individual leadwires, and accessories. The Affinity Cable and Leadwire System is based upon proven designs to assure secure connections for patient safety and operator ease of use. The Affinity Cable and Leadwire System is reusable and is designed and tested to conform to the following standards: ANSI/AAMI EC53-1995 and 21 CFR Part 898.

The Affinity Cable and Leadwire System is manufactured of materials with a proven history of use for ECG cables. The Affinity Cable and Leadwire System contains no latex or latex products which are external and exposed to the patient.

The Affinity Cable and Leadwire System is provided non-sterile.

The Affinity Cable and Leadwire System is designed to minimize the potential for incorrect attachments. Leadwires are color coded for positive identification. Leadwire connectors include recessed sockets to preclude attachment to power cables or outlets.

5. **Intended Use:** The Affinity Cable and Leadwire System is intended transmit data in the form of electrocardiograph signals from patient ECG electrode pads to ECG monitors.

4. 6. **Comparison to Predicate Device**: This device has the same technological characteristics (i.e., design, material, chemical composition) as the Tronomate™ Patient Cable and Leadwire System (K952659). Further, the Affinity Medical Patient Cable Systems are designed and tested in accordance with ANSI/AAMI EC53-1995, ECG Cable and Leadwires.

Attachment VII

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 1998

Ms. Mary F. Phillipp
Affinity Medical Technologies, LLC
17332 Von Karman, Suite 115
Irvine, CA 92614

Re: K980806
Affinity Medical Patient Cable Systems
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: February 27, 1998
Received: March 3, 1998

Dear Ms. Phillipp:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"Indications For Use" Statement

510(k) Number: Unknown

Device Names: Affinity Medical Patient Cable Systems

Indications for Use: The Affinity Medical Patient Cable Systems are intended to transmit data in the form of electrocardiographic signals from patient ECG electrode pads to ECG monitors.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-counter Use _____
(Per 21 CFR 801.109)

Optional Format 1-2-96

3/24/98 C. Cary for W. Sapienza
(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K980806

Attachment I